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| Substitute for Form 1449/PTO   |   |    |   | <i>Complete if Known</i>          |
| <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |   |    |   | Application Number                |
|  |   |    |   | 10/502,403                        |
|  |   |    |   | Filing Date                       |
|  |   |    |   | § 371(c) Date: June 20, 2005      |
|  |   |    |   | First Named Inventor              |
|  |   |    |   | LARA OCHOA, José Manuel Francisco |
|  |   |    |   | Art Unit                          |
|  |   |    |   | 1611                              |
|  |   |    |   | Examiner Name                     |
|  |   |    |   | Rae, Charlesworth E.              |
| Sheet  | 1 | of | 1 | Attorney Docket Number            |
|  |   |    |   | 2099.0090000/PAJ/LMB              |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet 1 of 1

Attorney Docket Number 2099.0090000/PAJ/LMB

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U.S. PATENT DOCUMENTS

#### FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document  | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|--|------------------|---|---|----------------|
|                    |                       | Country Code <sup>2</sup> Number Kind Code <sup>3</sup> (if known) | MM-DD-YYYY       |   |   |                |
|                    | FP1                   | WO 97/17975 A1   | 05-22-1997       | Istituto Gentili S.P.A.                         |   |                |
|                    | FP2                   | WO 00/40233 A1   | 07-13-2000       | Hexal AG  |   | Abs ISR        |
|                    | FP3                   | WO 01/32158 A2   | 05-10-2001       | Bristol-Myers Squibb Company                    |   |                |
|                    | FP4                   | WO 03/061643 A1  | 07-31-2003       | Laboratorios Silanes, S.A. de C.V.              |   | Abs            |
|                    | FP5                   | WO 2004/045622 A1  | 06-03-2004       | Ranbaxy Laboratories Limited                    |   |                |
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|                              |   |    |   | Examiner Name            | Rae, Charlesworth E.              |
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| <b>NON PATENT LITERATURE DOCUMENTS</b> |                       |  |  |  |                |
|--|-----------------------|--|--|--|----------------|
| Examiner Initials*                     | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published |  |  | T <sup>2</sup> |
|  | NPL1                  | ABBINK, E.J., <i>et al.</i> , "Vascular effects of glibenclamide vs. glimepiride and metformin in Type 2 diabetic patients," <i>Diabet. Med.</i> 19:136-143, Blackwell Science (February 2002)   |  |  |                |
|  | NPL2                  | BRESSLER, R., and JOHNSON, D.G., "Pharmacological Regulation of Blood Glucose Levels in Non-Insulin-Dependent Diabetes Mellitus," <i>Arch. Intern. Med.</i> 157:836-848, American Medical Association (1997)   |  |  |                |
|  | NPL3                  | CEFALU, W.T., <i>et al.</i> , "Insulin Sensitivity is Improved After Glipizide GITS Mono-Therapy and in Combination with Metformin," <i>Diabetologia</i> 39:A231, Springer Verlag (1996)   |  |  |                |
|  | NPL4                  | CEFALU, W.T., <i>et al.</i> , "Combination Glipizide GITS/Metformin Normalizes Glucose and Improves Insulin Sensitivity in Hyperinsulinemic Moderately Well Controlled NIDDM," <i>Diabetes</i> 45:201A, American Diabetes Association (1996)                   |  |  |                |
|  | NPL5                  | CHARPENTIER, G., <i>et al.</i> , "Improved glycemic control by addition of glimepiride to metformin monotherapy in Type 2 diabetic patients," <i>Diabet. Med.</i> 18:828-834, Blackwell Science (October 2001)   |  |  |                |
|  | NPL6                  | CROUSE III, J.R., <i>et al.</i> , "Effects of Combination Glipizide GITS/Metformin Treatment on Oxidizability of LDL in Non-Insulin Dependent Diabetes Mellitus," <i>Circulation</i> 94:1-508, Lippincott Williams & Wilkins (1996)                            |  |  |                |
|  | NPL7                  | DAGOOGO-JACK, S., and SANTIAGO, J.V., "Pathophysiology of Type 2 Diabetes and Modes of Action of Therapeutic Interventions," <i>Arch. Intern. Med.</i> 157:1802-1817, American Medical Association (1997)  |  |  |                |
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|  | NPL10                 | GARBER, A.J., <i>et al.</i> , "Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-controlled, Dose-Response Trial," <i>Am. J. Med.</i> 102:491-497, Excerpta Medica, Inc. (1997)  |  |  |                |

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|                              |   |    |   | Filing Date                     | § 371(c) Date: June 20, 2005      |
|                              |   |    |   | First Named Inventor            | LARA OCHOA, José Manuel Francisco |
|                              |   |    |   | Art Unit                        | 1611                              |
|                              |   |    |   | Examiner Name                   | Rae, Charlesworth E.              |
| Sheet                        | 2 | of | 3 | Attorney Docket Number          | 2099.0090000/PAJ/LMB              |

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|--|-----------------------|---|--|--|----------------|
| Examiner Initials*                     | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published   |  |  | T <sup>2</sup> |
|  | NPL11                 | GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Eficacia y seguridad de la terapia hipoglicemante oral combinada de glimepirida más metformina en una sola forma farmacéutica en pacientes con diabetes mellitus tipo 2 y falla secundaria a una monoterapia con glibenclamida," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)    |  |  | ✓              |
|  | NPL12                 | English Language Translation of GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy and safety of glimepiride plus metformin in a single presentation, as combined therapy, in patients with type 2 diabetes mellitus and secondary failure to glibenclamide, as monotherapy," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004) |  |  |                |
|  | NPL13                 | GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy of glimepiride/metformin combination versus glibenclamide/metformin in patients with uncontrolled type 2 diabetes mellitus," <i>J. Diabetes Complicat.</i> , Elsevier Science Publishing Company, 4 pages, Article in Press, uncorrected proof (September 2008)   |  |  |                |
|  | NPL14                 | GOMIS, R., <i>et al.</i> , "Appropriate Timing of Glimepiride Administration in Patients with Type 2 Diabetes Mellitus," <i>Endocrine</i> 13:117-121, Endocrine Society (2000)  |  |  |                |
|  | NPL15                 | HERMANN, L.S., <i>et al.</i> , "Therapeutic Comparison of Metformin and Sulfonylurea, Alone and in Various Combinations," <i>Diabetes Care</i> 17:1100-1109, American Diabetes Association (1994)   |  |  |                |
|  | NPL16                 | HIGGINBOTHAM, L. and MARTIN, F.I.R., "Double-Blind Trial of Metformin in the Therapy of Non-Ketotic Diabetics," <i>Med. J. Aust.</i> 2:154-156, Australian Medical Publishing Company Limited (1979)  |  |  |                |
|  | NPL17                 | HOLSTEIN, A., <i>et al.</i> , "Lower Incidence of Severe Hypoglycaemia in Type 2 Diabetic Patients Treated with Glimepiride Versus Glibenclamide," <i>Diabetologia</i> 43:A 40, Springer Verlag (2000)  |  |  |                |
|  | NPL18                 | MÜLLER, G., <i>et al.</i> , "Differential interaction of glimepiride and glibenclamide with the β-cell sulfonylurea receptor," <i>Biochim. Biophys. Acta</i> 1191:267-277, Elsevier Pub. Co. (1994)   |  |  |                |
|  | NPL19                 | ROSENSTOCK, J., <i>et al.</i> , "Glimepiride, a New Once-Daily Sulfonylurea," <i>Diabetes Care</i> 19:1194-1199, American Diabetes Association (1996)   |  |  |                |
|  | NPL20                 | SATO, J., <i>et al.</i> , "Comparison between effects of glimepiride and glibenclamide on <i>in vivo</i> insulin action," in <i>Proceedings of the Fourth International Symposium on Treatment of Diabetes Mellitus</i> , Nagoya, 26-27 October 1993, Sakamoto, N., <i>et al.</i> , eds., Excerpta Medica, Amsterdam, Netherlands, pp. 341-348 (1994)             |  |  |                |

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|  | NPL21     | SCHEEN, A.J., and LEFÉBVRE, P.J., "Oral Antidiabetic Agents. A Guide to Selection," <i>Drugs</i> 55:225-236, ADIS Press (1998)  |  |  |                |
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|  | NPL24     | VIGNERI, R., et al., "Treatment of NIDDM Patients with Secondary Failure to Glyburide: Comparison of the Addition of Either Metformin or Bed-Time NPH Insulin to Glyburide," <i>Diabete Metab.</i> 17:232-234, Masson (1991)                                  |  |  |                |
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|  | NPL27     | SHIMPI, R.D., et al., "Comparison of effect of metformin in combination with glimepiride and glibenclamide on glycaemic control in patient with type 2 diabetes mellitus," <i>Int. J. PharmTech Res.</i> 1:50-61, Sphinx Knowledge House (January-March 2009) |  |  |                |
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